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**IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF UTAH, CENTRAL DIVISION**

UNIVERSITY OF UTAH RESEARCH
FOUNDATION, a Utah nonprofit corporation; the
TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA, a Pennsylvania nonprofit
corporation; HSC RESEARCH AND
DEVELOPMENT LIMITED PARTNERSHIP, a
Canadian limited partnership organized under the laws
of the Province of Ontario; ENDORECHERCHE,
INC., a Canadian corporation organized under the laws
of the Province of Quebec; and MYRIAD
GENETICS, INC., a Delaware corporation;

Plaintiffs,

vs.

AMBRY GENETICS CORPORATION,

Defendant.

**REPLY IN SUPPORT OF
PLAINTIFFS' MOTION FOR
RECONSIDERATION OF THE
COURT'S ORDER GRANTING
DEFENDANT AMBRY GENETIC
CORPORATION'S MOTION TO
EXTEND THE TIME PERIOD TO
RESPOND TO PLAINTIFFS'
MOTION FOR PRELIMINARY
INJUNCTION**

Case No. 2:13-cv-00640-RJS

Judge Robert J. Shelby

Plaintiffs University of Utah Research Foundation, the Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, Endorecherche, Inc., and Myriad Genetics, Inc. (collectively, “Myriad”) submit this Reply in Support of their Motion for Reconsideration (Dkt. #20).

Ambry Genetics Corporation’s (“Ambry”) Opposition misses the point. The issue before the Court isn’t whether Ambry can have additional time to file its Opposition – Myriad offered Ambry that. Instead, the issue is whether Ambry should be allowed to take the additional time while altering the more than 15-year status quo and inflicting irreparable harm upon Myriad and the market in the interim. Myriad’s offer strikes the appropriate balance. Any extension beyond a few days should be conditioned upon Ambry agreeing to preserve the pre-June 13 status quo.

Furthermore, apparently in an effort to counter Myriad’s showing of irreparable harm, Ambry attached certain, unverified and unsworn materials to its Opposition (specifically as Exhibits to the Declaration of William G. Gaede III, Dkt. #23) that contain factual inaccuracies that bear correction. Exhibit 1 to the Declaration (Dkt. #23-1) is a letter from C. Bruce Alexander of the American Society for Clinical Pathology to the United States Patent and Trademark Office dated February 16, 2012 (sixteen months before the Supreme Court’s decision). Mr. Alexander’s letter contains several vague, general, and unsubstantiated contentions regarding so-called gene patents and the affordability and quality of genetic testing. At one point, for example, the letter contends that, though not addressing Myriad or its practices directly, patent exclusivity limits patient access to genetic predisposition testing particularly “when exclusive providers fail to contract with insurers such as state Medicaid programs.” This

is demonstrably not the case with regard to Myriad. As set forth in the accompanying Second Declaration of Alexander Ford (“Ford Decl.”), rather than “failing to contract with insurers,” Myriad created the market for hereditary breast/ovarian cancer predisposition testing by ensuring that such reimbursement existed, at least from all willing private and public providers, including private payors, Medicare, and the majority of state Medicaid programs. Ford Decl., ¶¶ 2-4.

Mr. Alexander’s letter contains additional inaccurate and misleading statements, suggesting for example that patients “are barred from obtaining a second opinion.” Dkt. #23-1 at 3. To the contrary, Myriad has specifically facilitated “second opinion” testing and reaffirmed its support of patients’ rights to seek a second opinion test in a public statement issued on the same day as the Supreme Court decision. *See* Ford Decl., ¶ 6. In fact, Myriad licensed LabCorp, the second largest reference laboratory in the country, to perform second opinion testing in 2002. *Id.* Second opinion testing is currently available from at least one national institution, the University of Chicago Genetic Services Laboratory. *Id.*

Mr. Alexander’s letter further wrongly asserts that the Myriad test is cost-prohibitive for many women. Dkt. #23-1 at 3. It is simply incorrect to state that women are unable to obtain Myriad’s test due to cost. As a result of Myriad’s efforts to contract with insurance companies to provide in-network benefits, more than 99% of patients receive some insurance reimbursement for BRACAnalysis® testing. *Id.*, ¶ 4. Average out of pocket cost to patients is less than \$100 with approximately 80% of patients actually paying nothing. *Id.*

Myriad’s efforts also address the needs of the few individuals who still cannot afford the testing with four different assistance programs. First, patients meeting clinical diagnostic criteria who desire BRACAnalysis® testing and meet a specified income requirement receive such testing free of charge. *Id.* Second, Myriad has a program to limit out of pocket costs to \$375 for

qualifying low-income patients with insurance. *Id.* Third, for any patient, Myriad offers interest-free financing programs to tailor payment plans for out-of-pocket costs to ensure they are affordable. *Id.* Lastly, Myriad donates and provides discounted testing to charities dedicated to assisting patients with out of pocket costs. Over the past five years, more than 35,000 patients have received some form of financial assistance from Myriad. *Id.*

Finally, it is noteworthy that Ambry's opposition does nothing to deny or explain the repeated statements by Ambry's CEO and Chief Medical Officer regarding its anticipation that its entry into the market would lead to the very lawsuit and motion it now faces. In the final analysis, Ambry offers no justification why its request for additional time should not be conditioned on preserving the more than 15-year (minus at most 6 weeks) status quo in the interim. To do otherwise will subject Myriad to irreparable harm and confuse the market by permitting Ambry to promise tests that it will not be able to provide should a preliminary injunction be entered.

Dated: July 24th, 2013.

Respectfully submitted,

/s/ David G. Mangum

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CERTIFICATE OF SERVICE

On this 24th day of July 2013, I certify that I electronically filed the foregoing **PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR RECONSIDERATION OF THE COURT'S ORDER GRANTING DEFENDANT AMBRY GENETIC CORPORATION'S MOTION TO EXTEND THE TIME PERIOD TO RESPOND TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION** with the Clerk of Court using the CM/ECF system that will send an electronic notification to counsel of record for all of the parties.

/s/ David G. Mangum
